FILE

U. S. ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 06/18/97

SUBJECT: ID#97CA0036. SECTION 18 EXEMPTION FOR THE USE OF **MYCLOBUTANIL** ON **PEPPERS (BELL and NON - BELL)** IN **CALIFORNIA**.

DP Barcode:	D235604	Caswell#:	723K
PRAT Case#:	288758	Chemical#:	128857
Trade Name:	Rally 40W	40 CFR:	§180.443
EPA Reg#:	707-215	Class:	Fungicide

ID#97ID0014. SECTION 18 EXEMPTION FOR THE USE OF **MYCLOBUTANIL** ON **MINT** IN **IDAHO**.

DP Barcode:	D234780	Caswell#:	723K
PRAT Case#:	288598	Chemical#:	128857
Trade Name:	Rally 40W	40 CFR:	§180.443
EPA Reg#:	707-221	Class:	Fungicide

ID#97CA0026. SECTION 18 EXEMPTION FOR THE USE OF **MYCLOBUTANIL** ON **ASPARAGUS** IN **CALIFORNIA**.

DP Barcode:	D234009	Caswell#:	723K
PRAT Case#:	288491	Chemical#:	128857
Trade Name:	Rally 40W	40 CFR:	§180.443
EPA Reg#:	707-215	Class:	Fungicide

TO: David Deegan/Meredith Johnson, PM Team 41
MUIERB/RD (7505C)

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INTRODUCTION

97CA0036 (Peppers):

The California Department of Pesticide Regulation has proposed a specific exemption for the use of myclobutanil on peppers (bell and non-bell) for control of powdery mildew (*Oidiopsis taurica*). This is the first §18 request for this use. The proposed program will entail application of 13,333 pounds of Rally 40W (5333 lbs ai) on 10,000 acres statewide from May 1, 1997 until April 30, 1998.

97ID0014 (Mint):

The Idaho Department of Agriculture has proposed a specific exemption for the use of myclobutanil on peppermint and spearmint for control of powdery mildew (*Erysiphe cichoracearum*). This is the first §18 request for this use. The proposed program will entail application of 6,562.5 pounds of Rally 40W (2,625 lbs ai) on 7,000 acres in the counties of Ada, Canyon, Elmore, Gem, Gooding, Owyhee, Payette, Twins Falls and Washington from April 15, 1997 until December 31, 1997.

97CA0026 (Asparagus):

The California Department of Pesticide Regulation has proposed a specific exemption for the use of myclobutanil on asparagus for control of asparagus rust (*Puccinia asparagi*). This is the second §18 request for this use. The first request (1996) was denied by the Agency. The proposed program will entail application of 30,000 pounds of Rally 40W (12000 lbs ai) on 18,000 acres statewide from July 7, 1997 until November 30, 1997.

SUMMARY

Provided RD insures that the appropriate REI statement appears on the label and that the appropriate rotational crop restrictions are added to the Section 18 labels, occupational exposure and aggregate risk estimates would not exceed HED's level of concern. These Section 18 exemptions should not pose an unacceptable aggregate risk to infants, children, or adults. Therefore, HED has no objection to the issuance of these Section 18 exemptions for the use of myclobutanil on peppers (bell and non - bell), mint and

asparagus in the States of California (peppers and asparagus) and Idaho (mint). The following time-limited tolerances for the combined residues of myclobutanil [α-butyl-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile] plus its alcohol metabolite [α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile] (free and bound) should be established to support this Section 18 exemption:

peppers (bell and non-bell)	1.0 ppm
spearmint	2.5 ppm
peppermint	2.5 ppm
asparagus	0.01 ppm

TOXICOLOGICAL ENDPOINTS

DIETARY

1) *Acute Toxicity.* For acute dietary risk assessment, the Toxicology Endpoint Selection Committee (TESC) did not identify an acute dietary toxicological endpoint and stated that an acute dietary risk assessment is not required (7/12/94).

2) *Chronic Toxicity.* RfD = 0.025 mg/kg/day. The RfD was established based on a chronic feeding study in rats (MRID#s 00149582 and 00165247) with a NOEL of 2.5 mg/kg/day and an uncertainty factor of 100. At the LOEL of 9.9 mg/kg/day there was testicular atrophy. (RfD/Peer Review Committee, 12/4/95).

NON-DIETARY

1) *Short-Term Toxicity.* For short-term dermal Margin of Exposure (MOE) calculations, the TESC recommended (7/12/94) use of the systemic NOEL of 100 mg/kg/day from the 21-day dermal toxicity study in rats (MRID# 00266080). This dose was the highest tested in the study. The TESC did not identify an inhalation endpoint.

2) *Intermediate-Term Toxicity.* For intermediate-term MOE calculations, the TESC (7/12/94) recommended use of the NOEL of 10 mg/kg/day from the 2-generation reproductive toxicity

study in rats (MRID#s 00143766 and 00149581). At the LEL of 50 mg/kg/day, there were decreases in pup body weight, an increased incidence in the number of stillborns, and atrophy of the prostate and testes.

3) *Chronic Toxicity.* The TESC determined (7/12/94) that a chronic toxicity endpoint and risk assessment for myclobutanil is not required for workers.

4) *Dermal Penetration.* For short-term MOE calculations, a dermal toxicity study was used, so adjustment for dermal penetration is not required. For intermediate-term MOE's, 100% dermal penetration (default value) was used.

CANCER

Myclobutanil has been classified as a Group E chemical (no evidence of carcinogenicity for humans) by the RfD/Peer Review Committee (12/4/95).

EXPOSURES AND RISKS

In examining aggregate exposure, FQPA directs EPA to consider available information concerning exposures from the pesticide residues in food and all other non-occupational exposures. The primary non-food sources of exposure the Agency looks at include drinking water (whether from groundwater or surface water), and exposure through pesticide use in gardens, lawns, or buildings (residential and other outdoor and indoor uses). In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

1. From Food and Feed Uses:

Tolerances have been established (40 CFR §180.443(a) and (c)) for the combined residues of myclobutanil [α-butyl-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile] plus its alcohol metabolite [α-(3-hydroxybutyl)-α-(4-chlorophenyl)-1*H*-1,2,4-triazole-1-propanenitrile] (free and bound), in or on a variety of raw agricultural commodities at levels ranging from 5.0 ppm in cherries to 0.02 ppm in eggs. A tolerance has also been established (40 CFR §180.443(b)) for the combined residues of myclobutanil plus its alcohol metabolite (free and bound) and diol metabolite [α-(4-chlorophenyl)-α-(3,4-dihydroxybutyl)-1*H*-1,2,4-triazole-1-propanenitrile], in milk at 0.05 ppm.

Acute Risk. The acute dietary (food only) risk assessment is not required as the TESC did not identify any acute dietary risk endpoints.

Chronic Risk. In conducting this chronic dietary risk assessment, EPA has made somewhat conservative assumptions -- with the exception of bananas, all commodities having myclobutanil tolerances will contain myclobutanil and metabolite residues and those residues will be at the level of the established tolerance -- which results in an overestimate of human dietary exposure. For bananas an anticated residue estimate was used. Percent crop-treated estimates were utilized for selected commodities included in the assessment. Thus, in making a safety determination for this tolerance, EPA is taking into account this partially refined exposure assessment.

The existing myclobutanil tolerances (published, pending, and including the necessary Section 18 tolerances) result in an Anticipated Residue Contribution (ARC) that is equivalent to the following percentages of the RfD:

Population Subgroup	ARC_{food} (mg/kg/day)	%RfD
U.S. Population (48 states)	0.003427	14%
Nursing Infants (<1 year old)	0.006242	25%
Non-Nursing Infants (<1 year old)	0.018291	73%
Children (1-6 years old)	0.009747	39%
Children (7-12 years old)	0.005505	22%
Northeast Region	0.003678	15%
Western Region	0.003999	16%
Hispanics	0.004125	17%
Non-Hispanic Others	0.003728	15%

The subgroups listed above are: (1) the U.S. population (48 states); (2) those for infants and children; and, (3) the other subgroups for which the percentage of the RfD occupied is greater than that occupied by the subgroup U.S. population (48 states).

2. From Drinking Water:

Based on information in the EFED One Liner Database (updated: 12/20/94), myclobutanil is persistent and not considered mobile in soils with the exception of sandy soils. Data are not available for its diol metabolite. There is no established Maximum Contaminant Level for residues of myclobutanil in drinking water (Safe Drinking Water Hotline - personal communication 5/14/97). No Health Advisory Levels for myclobutanil in drinking water have been established. The "Pesticides in Groundwater Database" (EPA 734-12-92-001, September 1992) has no information concerning myclobutanil.

Because the Agency lacks sufficient water-related exposure data to complete a comprehensive drinking water risk assessment for many pesticides, EPA has commenced and nearly completed a process to identify a reasonable yet conservative bounding figure for the potential contribution of water related exposure to the aggregate risk posed by a pesticide. In developing the bounding figure, EPA estimated residue levels in water for a number of specific pesticides using various data sources. The Agency then applied the estimated residue levels, in conjunction with appropriate toxicological endpoints (RfDs or acute dietary NOELs) and assumptions about body weight and consumption, to calculate, for each pesticide, the increment of aggregate risk contributed by

consumption of contaminated water. While EPA has not yet pinpointed the appropriate bounding figure for consumption of contaminated water, the ranges the Agency is continuing to examine are all well below the level that would cause myclobutanil to exceed the RfD if the tolerances being considered in this document were granted. The Agency has therefore concluded that the potential exposures associated with myclobutanil in water, even at the higher levels the Agency is considering as a conservative upper bound, would not prevent the Agency from determining that there is a reasonable certainty of no harm if the tolerance is granted.

3. From Non-Dietary Uses:

Myclobutanil is currently registered for outdoor residential and greenhouse use on annuals and perennials, turf, shrubs, trees, flowers (Reference Files System/OPP LAN, date searched: 6/5/97). HED has determined these uses do not constitute a chronic exposure scenario, but may constitute a short- to intermediate-term exposure scenario.

The Agency lacks sufficient residential-related exposure data to complete a comprehensive residential risk assessment for many pesticides, including myclobutanil.

4. From Cumulative Exposure To Substances with a Common Mechanism of Toxicity.

Myclobutanil is a member of the triazole class of systemic fungicides (*The Pesticide Book, 4th ed., 1994*). Other triazoles include bitertanol, cyproconazole, diclobutrazole, difenoconazole, diniconazole, fenbuconazole, flusilazole, hexaconazole, penconazole, propiconazole, tebuconazole, tetraconazole, triadimefon, and triadimenol.

Section 408(b)(2)(D)(v) of the Food Quality Protection Act requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." The Agency believes that "available information" in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments.

For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether myclobutanil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. For the purposes of these tolerance actions, therefore, EPA has not assumed that myclobutanil has a common mechanism of toxicity with other substances.

DETERMINATION OF SAFETY FOR U.S. POPULATION

1. Acute Aggregate Risk. This risk assessment is not required as the TESC did not identify any acute dietary risk endpoints.

2. Chronic Aggregate Risk. Using the partially refined exposure assumptions described above and taking into account the completeness and reliability of the toxicity data, HED has concluded that aggregate dietary exposure (food only) to myclobutanil will utilize 14% of the RfD for the U.S. population. HED generally has no concern for exposures below 100 percent of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. HED has determined that the outdoor registered uses of myclobutanil would not fall under a chronic exposure scenario. Despite the potential for exposure to myclobutanil in drinking water, using best scientific judgement HED does not expect the aggregate exposure of food and water to exceed 100% of the RfD. HED concludes that there is a reasonable certainty that no harm will result from aggregate chronic exposure to myclobutanil residues.

3. Short- and Intermediate-Term Aggregate Risk. Although short-term exposure scenarios may be present, based on the lack of acute toxicological endpoints and the low percent of RfD occupied, in the best scientific judgement of HED, aggregate short- and intermediate-term risk will not exceed HED's level of concern. Additionally HED notes that there are no indoor residential uses of myclobutanil, thus indoor residential exposure is expected to be minimal.

DETERMINATION OF CANCER RISK

Myclobutanil was classified by the RfD/Peer Review Committee (12/4/95) as a Group E chemical (no evidence of carcinogenicity for humans). Thus, a cancer risk assessment was not conducted.

ENDOCRINE DISRUPTOR EFFECTS

EPA is required to develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...."

The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed 3 years from the passage of FQPA (August 3, 1999) to implement this program. At that time, EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects.

DETERMINATION OF SAFETY FOR INFANTS AND CHILDREN

In assessing the potential for additional sensitivity of infants and children to residues of myclobutanil, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproductive toxicity study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during prenatal development. Reproduction studies provide information relating to pre- and post-natal effects from exposure to the pesticide, information on the reproductive capability of mating animals, and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional 10-fold margin of safety for infants and children in the case of threshold effects to account for pre-and post-natal toxicity and the completeness of the database unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed effect level in the animal study appropriate to the particular risk assessment. This 100-fold uncertainty (safety) factor/margin of exposure (safety) is designed to account for combined inter-species extrapolation and intra-species variability. EPA believes that reliable data support using the standard 100-fold margin/factor not the additional 10--fold margin/factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard margin/factor.

1. Developmental Toxicity Studies.

a. Rats. In the developmental study (MRID# 00141672)in rats, the maternal (systemic) NOEL was 93.8 mg/kg/day, based on rough hair coat, and salivation at the LOEL of 312.6 mg/kg/day. The developmental (fetal) NOEL was 93.8 mg/kg/day based on incidences of 14th rudimentary and 7th cervical ribs at the LOEL of 312.6 mg/kg/day.

b. Rabbits. In the developmental toxicity study (MRID# 00164971) in rabbits, the maternal (systemic) NOEL was 60 mg/kg/day, based on reduced weight gain, clinical signs of toxicity and abortions at the LOEL of 200 mg/kg/day. The developmental (fetal) NOEL was 60 mg/kg/day, based on increases in number of resorptions, decreases in litter size, and a decrease in the viability index at the LOEL of 200 mg/kg/day.

2. Reproductive Toxicity Studies.

Rats. In the 2-generation reproductive toxicity study (MRID# 00143766, 00149581) in rats, the parental (systemic) NOEL was 2.5 mg/kg/day, based on increased liver weights and liver cell hypertrophy at the LOEL of 10 mg/kg/day. The developmental (pup) NOEL was 10 mg/kg/day, based on decreased pup body weight during lactation at the LOEL of 50 mg/kg/day. The reproductive (pup) NOEL was 10 mg/kg/day, based on the increased incidence of stillborns, and atrophy of the testes, epididymides, and prostate at the LEL of 50 mg/kg/day.

3. Pre- and Post-Natal Sensitivity.

The pre- and post-natal toxicology data base for myclobutanil is complete with respect to current toxicological data requirements. Based on the developmental and reproductive toxicity studies discussed above, for myclobutanil there does not appear to be an extra sensitivity for pre- or post-natal effects.

Based on the above, EPA concludes that reliable data support use of the standard 100-fold uncertainty factor and that an factor is not needed to protect the safety of infants and children.

4. *Acute Risk.* The acute dietary (food only) risk assessment is not required as the TESC did not identify any acute dietary risk endpoints.

5. *Chronic Risk.* Using the partially refined exposure assumptions described above, HED has concluded that the percent of the RfD that will be utilized by dietary (food only) exposure to residues of myclobutanil ranges from 22 percent for children (7 to 12 years old), up to 73 percent for non-nursing infants (<1 year old). Despite the potential for exposure to myclobutanil in drinking water, HED does not expect the aggregate exposure of food and water to exceed 100% of the RfD. Therefore, taking into account the completeness and reliability of the toxicity data and the partially refined exposure assessment, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to myclobutanil residues.

DETERMINATION OF SAFETY TO OCCUPATIONALLY EXPOSED WORKERS

1. Acute data for this formulation are available to RAB2. Based on the toxicity categories in the Tox Oneliners, the work clothing and personal protective equipment (PPE) appearing on the label are in compliance with the Worker Protection Standard (WPS). The label cited in the submission (Rally 40W, Agricultural Fungicide, in Water Soluble Pouches, EPA Reg. No. 707-215) requires applicators and other handlers to wear long-sleeved shirt, long pants, waterproof gloves, shoes plus socks, protective eyewear, and chemical-resistant headgear for overhead exposure.

2. Acute toxicological data for the technical are available. According to the Tox Oneliners, myclobutanil is a category I for primary eye irritation; category III for acute oral and dermal LD50; category IV for primary dermal irritation and acute oral LD50. Based on these values, the restricted entry interval (REI) should be 48 hours to be in compliance with the WPS. However, the label lists an REI of 24 hours. The registrant may have submitted additional data to support a 24 hour REI for this chemical. **RD should insure that the appropriate REI statement appears on the label.**

3. Occupational exposure assumptions and estimates of exposure are summarized in Tables 1 and 2, respectively. Worker exposure estimates are based on surrogate data from the Pesticide Handlers Exposure Database (PHED). RAB2 has calculated the estimates of exposure with mixer/loaders and applicators wearing a single layer of clothing plus gloves (pilots are not expected to wear gloves). Insufficient data are available in PHED for water-soluble pouches. The mixer/loader estimates of exposure are based on wettable powders, open pour. Consequently, **the calculated MOEs for mixer/loaders should be considered very conservative.** In addition, the TES Committee did not identify inhalation exposure as either a short- or intermediate-term risk. As a result, estimates of exposure do not include the inhalation route. However, based on the use of water-soluble pouches, in the best scientific judgement of RAB2, inhalation exposure should be low.

4. Using the exposure assumptions listed above, HED has concluded that the MOEs that will result from the handling and application of myclobutanil by workers range from 150 for aerial equipment mixer/loaders to 4,700 for aerial applicators. These MOEs do not exceed HED's level of concern for occupationally exposed workers.

OTHER CONSIDERATIONS

Metabolism in Plants

1. The nature of the residue in plants is adequately understood. The residue of concern is myclobutanil plus its alcohol metabolite (free and bound), as specified in 40 CFR 180.443(a).

Analytical Enforcement Methodology

2. An adequate enforcement method (Rohm and Haas Method 34S-88-10, MRID# 408033-02) is available to enforce the established tolerances. Quantitation is by GLC using an Nitrogen/Phosphorus detector for myclobutanil and an Electron Capture detector (Ni^{63}) for residues measured as the alcohol metabolite. A copy of this method is on file in PP#4E4302.

Magnitude of the Residues

97CA0036 (Peppers):

3. Residues of myclobutanil and its alcohol metabolite are not expected to exceed 1.0 ppm in/on peppers (bell and non-bell) as a result of this Section 18 use. **A time-limited tolerance for the combined residues of myclobutanil and its alcohol metabolite (free and bound) should be established at this level.**

97ID0014 (Mint):

4. Residues of myclobutanil and its alcohol metabolite are not expected to exceed the following levels as a result of this Section 18 use.

peppermint	2.5 ppm
spearmint	2.5 ppm

Time-limited tolerances for the combined residues of myclobutanil and its alcohol metabolite (free and bound) should be established at these levels. Residues are not expected to concentrate in mint oil.

97CA0026 (Asparagus):

5. Residues of myclobutanil and its alcohol metabolite are not expected to exceed 0.01 ppm in/on asparagus as a result of this Section 18 use. **A time-limited tolerance for the combined residues of myclobutanil and its alcohol metabolite (free and bound) should be established at this level.**

Magnitude of the Residues (Meat/Milk/Poultry and Eggs)

6. Secondary residues are not expected in animal commodities as no feedstuffs are associated with these Section 18 uses. Meat/milk/poultry/egg tolerances have been established as a result of other myclobutanil uses.

Rotational Crop Restrictions

7. Information concerning the likelihood of residues in rotational crops is not available for myclobutanil. As mint and pepper (bell and non-bell) fields are normally rotated, **HED concludes the following restriction should be added to the label for the requested Section 18: Rally treated fields can be rotated at any time to crops which are included on the Rally label. All other crops may be planted 1 year following applications of Rally Agricultural Fungicide.**

International Residue Limits

8. There are no Codex, Canadian or Mexican residue limits established for myclobutanil and its metabolites on the commodities included in these Section 18 requests. Thus, harmonization is not an issue for these Section 18 actions.

SUPPLEMENTAL INFORMATION

Occupational Exposure

Table 1. Occupational Exposure Assumptions

PARAMETER	ASSUMPTION
Pesticide Handlers Exposure Database (PHED), Version 1.1, Unit of Exposure From Best Available Surrogate Exposure Table (BASET, 2/28/96)	Mixer/Loader (wettable powder, open bag, single layer clothing plus gloves): Dermal = 160.0 µg/lb ai handled.
	Applicator - Ground (ground boom, open cab, single layer clothing plus gloves): Dermal = 14.0 µg/lb ai applied.
	Applicator - Air (liquid formulations, enclosed cockpit, single layer clothing, no gloves): Dermal = 5.0 µg/lb ai applied.
Percent Absorption	Dermal: NA (based upon dermal tox study)
Application Type	Ground or aerial
Minimum Finish Spray	Ground: 10 gal/A (estimated minimum dilution rate) Air: 10 gal/A (dilution rate for mint and peppers)
Maximum Application Rate	0.125 lb ai/A
Acres Treated/Day (Y. NG,BEAD)	Ground: 104 acres Air: 204 acres
Worker Weight	60 kg (based on Tox endpoint)
Number of Farms Treated by PCO (Professional Chemical Operator)	Ground: 2; Air: 10 (OREB default values)

Table 2. Occupational Exposure and Risk Assessment[a]			
Worker	Average Daily Dermal Dose[b] (ug/kg/day)	Short-Term Dermal MOE[c]	Intermediate-Term Dermal MOE[d]
Ground Mixer/Loader	34.67	2,900	290
Ground Applicator	3.03	33,000	3,300
Aerial Mixer/Loader	68.00	1,500	150
Aerial Applicator	2.13	47,000	4,700

[a] MOEs are expressed to two significant figures.
[b] Average Daily Dermal Dose (ADD) = PHED unit exposure x % absorption x application rate x acres treated/day ÷ kg body weight.
[c] Short-Term Occupational Dermal Exposure MOE = NOEL/ADD (where NOEL = 100 mg/kg/day).
[d] Intermediate-Term Occupational Dermal Exposure MOE = NOEL/ADD (where NOEL = 10 mg/kg/day).

Dietary Exposure

97CA0036 (Peppers):

Table 3. Residue Consideration Summary Table		
PARAMETER	PROPOSED USE	RESIDUE DATA
CHEMICAL	Myclobutanil	Myclobutanil
FORMULATION	Rally 40W Agricultural Fungicide in Water-Soluble Pouches (Rohm and Haas, EPA Reg. No. 707-215)	Rally 60DF (Rohm and Haas, EPA Reg. No. 707-211)
CROP	Peppers (bell and non-bell)	Tomatoes
TYPE APPLICATION	Ground or aerial	ground
# APPLICATIONS	4 applications	4 or 5 applications
TIMING	10 to 14 day intervals	21 day intervals
RATE/APPLICATION	4 ounces product/A 0.13 lbs ai/A	0.063 to 0.085 lbs ai/A
RATE/YEAR or SEASON	16 ounces product/A/crop 0.53 lbs ai/A/crop	0.24 to 0.34 lbs ai/A/crop
MAXIMUM RESIDUE	N/A	0.25 ppm (4 apps @ 0.085 lbs ai/A)
RESTRICTIONS	0 day PHI	0 day PHI
RESIDUE DATA SOURCE	N/A	MRID Nos. 420192-01, -02, 423107-01 PP#1F4030/1H5616
PERFORMING LAB	N/A	Rohm and Haas

97ID0014 (Mint):

Table 4. Residue Consideration Summary Table

PARAMETER	PROPOSED USE	RESIDUE DATA
CHEMICAL	Myclobutanil	Myclobutanil
FORMULATION	Rally 40W Agricultural Fungicide in Water-Soluble Pouches (Rohm and Haas, EPA Reg. No. 707-215)	Rally 40W (EPA Reg. No. 707-215)
CROP	Spearmint and Peppermint	Spearmint and Peppermint
TYPE APPLICATION	Ground	Ground - foliar
# APPLICATIONS	3	4 or 3
TIMING	14 to 21 day intervals	14 to 22 day intervals
RATE/APPLICATION	0.31 lbs product/A 0.125 lbs ai/A	0.31 lbs product/A 0.125 lbs ai/A
RATE/YEAR or SEASON	0.93 lbs product/A/crop 0.375 lbs ai/A/crop	0.93 to 1.25 lbs product/A/crop 0.375 to 0.5 lbs ai/A/crop
MAXIMUM RESIDUE	N/A	Spearmint and peppermint 2.2 ppm A processing study demonstrated that residues will not concentrate into mint oil.
RESTRICTIONS	30 day PHI	24 to 33 day PHI
RESIDUE DATA SOURCE	N/A	IR-4 - Presubmission field trials data included in §18 submission (PR-3966).
PERFORMING LAB	N/A	IR-4

97CA0026 (Asparagus):

Table 5. Residue Consideration Summary Table

PARAMETER	PROPOSED USE	RESIDUE DATA
CHEMICAL	Myclobutanil	Myclobutanil
FORMULATION	Rally 40W Agricultural Fungicide in Water-Soluble Pouches (Rohm and Haas, EPA Reg. No. 707-215)	Rally 40 W (EPA Reg. No. 707-215 or 707-221)
CROP	Asparagus	Asparagus (two 1995 CA field trials)
TYPE APPLICATION	Ground or aerial	Ground - foliar to asparagus ferns
# APPLICATIONS	4	4
TIMING	Fern stage of growth: Begin at first sign of disease and continue on a 14 to 21 day schedule.	During fern stage; applications made at intervals of 14 ± 2 days (mid-July to late August). After 4th application ferns were cut to stimulate spear development.
RATE/APPLICATION	0.31 lbs product/A 0.125 lbs ai/A	0.31 lbs product/A 0.125 lbs ai/A
RATE/YEAR or SEASON	1.25 lbs product/A/crop 0.5 lbs ai/A/crop	1.25 lbs product/A/crop 0.5 lbs ai/A/crop
MAXIMUM RESIDUE	N/A	<0.01 ppm
RESTRICTIONS	30 day PHI	30 day PHI
RESIDUE DATA SOURCE	N/A	Presubmission field trials data faxed to the Agency by IR-4 (7/23/96)
PERFORMING LAB	N/A	IR-4

Additional Information

Progress Toward Registration.

97CA0036 (Peppers):

This is the first Section 18 request for this use of myclobutanil on peppers. IR-4 has initiated a residue program for myclobutanil on non-bell peppers to be conducted during 1997 and bell peppers to be conducted during 1998.

97ID0014 (Mint):

IR-4 supports this use of myclobutanil on mint and intends to submit a petition for tolerances on mint in 1997. IR-4 generated the residue data to support this Section 18 request.

97CA0026 (Asparagus):

IR-4 has generated residue data for myclobutanil in/on asparagus and intends to submit a petition for tolerances to the Agency.

Reregistration Status.

Myclobutanil is not a FIFRA '88 reregistration active ingredient.

Attachments: Chronic DRES Analyses (S. Knizner, 5/29/97)

cc with Attachments: W.D. Wassell, RAB2, RAB1 (Ed Zager), OREB (Chem File), Caswell File, TOX (W. Dykstra), CBTS (Sect 18), CEB1 (B. Steinwand), RCAB (K. Boyle)

cc without Attachments: C. Lewis (RAB2), W. Dykstra (RAB1)
RDI:PIRAT: 06/11/97; RALoranger: 06/12/97.

CHEMICAL INFORMATION	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

POPULATION SUBGROUP	TOTAL TMRC (MG/KG BODY WEIGHT/DAY) CURRENT TMRC*	NEW TMRC**	NEW TMRC AS PERCENT OF RFD	DIFFERENCE AS PERCENT OF RFD	EFFECT OF ANTICIPATED RESIDUES ARC	%RFD
U.S. POPULATION - 48 STATES	0.004088	0.005123	20.493804	4.143016	0.003427	13.70641
U.S. POPULATION - SPRING SEASON	0.003853	0.004841	19.363692	3.951448	0.003225	12.90031
U.S. POPULATION - SUMMER SEASON	0.004483	0.005527	22.107812	4.176936	0.003508	14.03288
U.S. POPULATION - FALL SEASON	0.004054	0.005093	20.371148	4.155084	0.003504	14.01748
U.S. POPULATION - WINTER SEASON	0.003963	0.005011	20.043040	4.190780	0.003445	13.78028
NORTHEAST REGION	0.004455	0.005477	21.909104	4.087548	0.003678	14.71038
NORTH CENTRAL REGION	0.004152	0.005108	20.433280	3.824852	0.003472	13.88860
SOUTHERN REGION	0.003308	0.004189	16.756156	3.522312	0.002844	11.37572
WESTERN REGION	0.004850	0.006257	25.027360	5.626352	0.003999	15.99498
HISPANICS	0.004731	0.006455	25.821004	6.898012	0.004125	16.50002
NON-HISPANIC WHITES	0.004167	0.005200	20.799372	4.129572	0.003464	13.85759
NON-HISPANIC BLACKS	0.003252	0.003883	15.532432	2.522784	0.002769	11.07558
NON-HISPANIC OTHERS	0.004234	0.005728	22.913352	5.975996	0.003728	14.91375
NURSING INFANTS (< 1 YEAR OLD)	0.009541	0.013920	55.678764	17.515512	0.006242	24.96782
NON-NURSING INFANTS (< 1 YEAR OLD)	0.024623	0.029764	119.055700	20.565404	0.018291	73.16436
FEMALES (13+ YEARS, PREGNANT)	0.002941	0.003507	14.029144	2.265440	0.002385	9.53913
FEMALES 13+ YEARS, NURSING	0.003761	0.004616	18.462168	3.416328	0.003138	12.55352
CHILDREN (1-6 YEARS OLD)	0.011345	0.014475	57.898292	12.517392	0.009747	38.98654
CHILDREN (7-12 YEARS OLD)	0.006383	0.007719	30.875036	5.342452	0.005505	22.02156
MALES (13-19 YEARS OLD)	0.003635	0.004334	17.335888	2.794132	0.003270	13.08086
FEMALES (13-19 YEARS OLD, NOT PREG. OR NURSING)	0.003034	0.003633	14.530388	2.394692	0.002626	10.50354
MALES (20 YEARS AND OLDER)	0.002400	0.003060	12.239984	2.639920	0.002017	8.06620
FEMALES (20 YEARS AND OLDER, NOT PREG. OR NURS)	0.002432	0.003109	12.436400	2.709088	0.001945	7.77947

*Current TMRC does not include new or pending tolerances.
**New TMRC includes new, pending, and published tolerances.

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
01014AA	GRAPES-FRESH	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014AA	GRAPES-FRESH	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014AA	GRAPES-FRESH	31 COOKED-FRESH OR CANNED	7F3476	P 1.000000	1.000000		79.00	0.790000
01014DA	GRAPES-RAISINS	10 RAW-FRESH OR NFS	7H5524	P 10.00000	10.000000C		79.00	7.900000
01014DA	GRAPES-RAISINS	21 COOKED-NFS	7H5524	P 10.00000	10.000000C		79.00	7.900000
01014DA	GRAPES-RAISINS	22 COOKED-FRESH-BAKED	7H5524	P 10.00000	10.000000C		79.00	7.900000
01014JA	GRAPES-JUICE	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01014JA	GRAPES-JUICE	15 RAW-FRESH OR CANNED	7F3476	P 1.000000	1.000000		79.00	0.790000
01014JA	GRAPES-JUICE	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
01016AA	STRAWBERRIES	10 RAW-FRESH OR NFS	97FL001	A 0.500000	0.500000		100.00	0.500000
01016AA	STRAWBERRIES	21 COOKED-NFS	97FL001	A 0.500000	0.500000		100.00	0.500000
01016AA	STRAWBERRIES	70 RAW-FROZEN	97FL001	A 0.500000	0.500000		100.00	0.500000
03001AA	ALMONDS	10 RAW-FRESH OR NFS	0F3876	P 0.100000	0.100000		1.00	0.001000
03001AA	ALMONDS	21 COOKED-NFS	0F3876	P 0.100000	0.100000		1.00	0.001000
03001AA	ALMONDS	22 COOKED-FRESH-BAKED	0F3876	P 0.100000	0.100000		1.00	0.001000
04001AA	APPLES-FRESH	10 RAW-FRESH OR NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	21 COOKED-NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	31 COOKED-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001AA	APPLES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	10 RAW-FRESH OR NFS	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	22 COOKED-FRESH-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001DA	APPLES-DRIED	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001JA	APPLES-JUICE	15 RAW-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04001JA	APPLES-JUICE	31 COOKED-FRESH OR CANNED	7F3476	P 0.500000	0.500000		60.00	0.300000
04002AA	CRABAPPLES	00 NOT SPECIFIED (NO CONSUMPTION)	9F3812	A 0.500000	0.500000		100.00	0.500000
04003AA	PEARS-FRESH	10 RAW-FRESH OR NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	31 COOKED-FRESH OR CANNED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	51 COOKED-CANNED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003AA	PEARS-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	9F3812	A 0.500000	0.500000		8.00	0.040000
04003DA	PEARS-DRIED	10 RAW-FRESH OR NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04003DA	PEARS-DRIED	21 COOKED-NFS	9F3812	A 0.500000	0.500000		8.00	0.040000
04004AA	QUINCES	00 NOT SPECIFIED (NO CONSUMPTION)	9F3812	A 0.500000	0.500000		100.00	0.500000
05001AA	APRICOTS-FRESH	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001AA	APRICOTS-FRESH	21 COOKED-NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001AA	APRICOTS-FRESH	31 COOKED-FRESH OR CANNED	1F3954	P 2.000000	2.000000		1.00	0.020000
05001DA	APRICOTS-DRIED	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		1.00	0.020000
05001DA	APRICOTS-DRIED	22 COOKED-FRESH-BAKED	1F3954	P 2.000000	2.000000		1.00	0.020000
05002AA	CHERRIES-FRESH	10 RAW-FRESH OR NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05002AA	CHERRIES-FRESH	21 COOKED-NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05002AA	CHERRIES-FRESH	31 COOKED-FRESH OR CANNED	2F4116	P 5.000000	5.000000		47.00	2.350000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
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FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
05002AA	CHERRIES-FRESH	62 COOKED-FRESH OR FROZEN-BAKED	2F4116	P 5.000000	5.000000		47.00	2.350000
05002DA	CHERRIES-DRIED	00 NOT SPECIFIED (NO CONSUMPTION)	2F4116	P 5.000000	5.000000		47.00	2.350000
05002JA	CHERRIES-JUICE	15 RAW-FRESH OR CANNED	2F4116	P 5.000000	5.000000		47.00	2.350000
05002JA	CHERRIES-JUICE	21 COOKED-NFS	2F4116	P 5.000000	5.000000		47.00	2.350000
05003AA	NECTARINES	10 RAW-FRESH OR NFS	9F3811	P 2.000000	2.000000		21.00	0.420000
05004AA	PEACHES-FRESH	10 RAW-FRESH OR NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	21 COOKED-NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	31 COOKED-FRESH OR CANNED	9F3811	P 2.000000	2.000000		22.00	0.440000
05004AA	PEACHES-FRESH	51 COOKED-CANNED	9F3811	P 2.000000	2.000000		22.00	0.440000
05004DA	PEACHES-DRIED	10 RAW-FRESH OR NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05004DA	PEACHES-DRIED	21 COOKED-NFS	9F3811	P 2.000000	2.000000		22.00	0.440000
05005AA	PLUMS-FRESH	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		3.00	0.060000
05005AA	PLUMS-FRESH	31 COOKED-FRESH OR CANNED	1F3954	P 2.000000	2.000000		3.00	0.060000
05005DA	PLUMS-PRUNES	10 RAW-FRESH OR NFS	1H5608	P 8.000000	8.000000C		3.00	0.240000
05005DA	PLUMS-PRUNES	21 COOKED-NFS	1H5608	P 8.000000	8.000000C		3.00	0.240000
05005DA	PLUMS-PRUNES	31 COOKED-FRESH OR CANNED	1H5608	P 8.000000	8.000000C		3.00	0.240000
05005JA	PRUNE-JUICE	10 RAW-FRESH OR NFS	1F3954	P 2.000000	2.000000		3.00	0.060000
05005JA	PRUNE-JUICE	62 COOKED-FRESH OR FROZEN-BAKED	1F3954	P 2.000000	2.000000		3.00	0.060000
06002AA	BANANAS-UNSPEC	22 COOKED-FRESH-BAKED	2E04141	A 4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	10 RAW-FRESH OR NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	21 COOKED-NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06002AB	BANANAS-FRESH	31 COOKED-FRESH OR CANNED	2E04141	A 4.000000	0.800000		100.00	0.800000
06002DA	BANANAS-DRIED	10 RAW-FRESH OR NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06002DA	BANANAS-DRIED	21 COOKED-NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	21 COOKED-NFS	2E04141	A 4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	23 COOKED-FRESH-BOILED	2E04141	A 4.000000	0.800000		100.00	0.800000
06016AA	PLANTAINS	25 COOKED-FRESH-FRIED	2E04141	A 4.000000	0.800000		100.00	0.800000
10002AA	CANTALOUPES-UNSP	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
10002AB	CANTALOUPES-PULP	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10002AB	CANTALOUPES PULP	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10003AA	CASABAS	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10004AA	CRENSHAWS	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
10005AA	HONEYDEW MELONS	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10007AA	PERSION MELONS	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
10008AA	WATERMELON	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10008AA	WATERMELON	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	11 RAW-FRESH-PICKLED,CORNED,OR CURED	SECT18	P 0.300000	0.300000		100.00	0.300000
10010AA	CUCUMBERS	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10011AA	PUMPKIN	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
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FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
10011AA	PUMPKIN	22 COOKED-FRESH-BAKED	SECT18	P 0.300000	0.300000		100.00	0.300000
10011AA	PUMPKIN	62 COOKED-FRESH OR FROZEN-BAKED	SECT18	P 0.300000	0.300000		100.00	0.300000
10013AA	SQUASH-SUMMER	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10013AA	SQUASH-SUMMER	21 COOKED-NFS	SECT18	A 0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	10 RAW-FRESH OR NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10014AA	SQUASH-WINTER	31 COOKED-FRESH OR CANNED	SECT18	P 0.300000	0.300000		100.00	0.300000
10017AA	BITTER MELON	21 COOKED-NFS	SECT18	P 0.300000	0.300000		100.00	0.300000
10020AA	TOWELGOURD	00 NOT SPECIFIED (NO CONSUMPTION)	SECT18	P 0.300000	0.300000		100.00	0.300000
11003AA	PEPPERS,SWEET	10 RAW-FRESH OR NFS	97CA036	N 1.000000	1.000000		100.00	1.000000
11003AA	PEPPERS,SWEET	21 COOKED-NFS	97CA036	N 1.000000	1.000000		100.00	1.000000
11003AB	CHILI PEPPERS	00 NOT SPECIFIED (NO CONSUMPTION)	97CA036	N 1.000000	1.000000		100.00	1.000000
11003AD	PEPPERS-OTHER	10 RAW-FRESH OR NFS	97CA036	N 1.000000	1.000000		100.00	1.000000
11003AD	PEPPERS-OTHER	21 COOKED-NFS	97CA036	N 1.000000	1.000000		100.00	1.000000
11003AD	PEPPERS-OTHER	51 COOKED-CANNED	97CA036	N 1.000000	1.000000		100.00	1.000000
11004AA	PIMIENTOS	10 RAW-FRESH OR NFS	97CA036	N 1.000000	1.000000		100.00	1.000000
11004AA	PIMIENTOS	21 COOKED-NFS	97CA036	N 1.000000	1.000000		100.00	1.000000
11004AA	PIMIENTOS	31 COOKED-FRESH OR CANNED	97CA036	N 1.000000	1.000000		100.00	1.000000
16002AA	ASPARAGUS	21 COOKED-NFS	97CA026	N 0.010000	0.010000		100.00	0.010000
16002AA	ASPARAGUS	23 COOKED-FRESH-BOILED	97CA026	N 0.010000	0.010000		100.00	0.010000
27003OA	COTTONSEED-OIL	18 PROCESSED OIL	4F4317	P 0.020000	0.020000		1.00	0.000200
27003WA	COTTONSEED-MEAL	18 PROCESSED OIL	4F4317	P 0.020000	0.020000		1.00	0.000200
28080AA	PEPPERMINT	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	N 2.500000	2.500000		100.00	2.500000
28080OA	PEPPERMINT-OIL	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	N 2.500000	2.500000		100.00	2.500000
28081AA	SPEARMINT	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	N 2.500000	2.500000		100.00	2.500000
28081OA	SPEARMINT-OIL	00 NOT SPECIFIED (NO CONSUMPTION)	971D014	N 2.500000	2.500000		100.00	2.500000
43058AA	WINE AND SHERRY	10 RAW-FRESH OR NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
43058AA	WINE AND SHERRY	21 COOKED-NFS	7F3476	P 1.000000	1.000000		79.00	0.790000
50000DB	MILK-NON-FAT SOL	10 RAW-FRESH OR NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000DB	MILK-NON-FAT SOL	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000DB	MILK-NON-FAT SOL	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	10 RAW-FRESH OR NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000FA	MILK-FAT SOLIDS	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
50000SA	MILK SUG (LACT)	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
50000SA	MILK SUG (LACT)	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BA	BEEF-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BA	BEEF-MEAT BYP	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BB	BEEF-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001BB	BEEF-OTH ORGAN	51 COOKED-CANNED	0F3876	P 0.200000	0.200000		100.00	0.200000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
53001DA	BEEF-DRIED	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001FA	BEEF-FAT	10 RAW-FRESH OR NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	22 COOKED-FRESH-BAKED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	24 COOKED-FRESH-BROILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001FA	BEEF-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53001KA	BEEF-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53001LA	BEEF-LIVER	25 COOKED-FRESH-FRIED	0F3876	P 1.000000	1.000000		100.00	1.000000
53001LA	BEEF-LIVER	31 COOKED-FRESH OR CANNED	0F3876	P 1.000000	1.000000		100.00	1.000000
53001MA	BEEF-LEAN	10 RAW-FRESH OR NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	22 COOKED-FRESH-BAKED	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	23 COOKED-FRESH-BOILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53001MA	BEEF-LEAN	24 COOKED-FRESH-BROILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53002BA	GOAT-MEAT BYP	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002BB	GOAT-OTH ORGAN	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002FA	GOAT-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53002FA	GOAT-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53002KA	GOAT-KIDNEY	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 0.200000	0.200000		100.00	0.200000
53002LA	GOAT-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53002MA	GOAT-LEAN	23 COOKED-FRESH-BOILED	0F3876	P 0.100000	0.100000		100.00	0.100000
53002MA	GOAT-LEAN	25 COOKED-FRESH-FRIED	0F3876	P 0.100000	0.100000		100.00	0.100000
53003AA	HORSE	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53005BA	SHEEP-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53005BB	SHEEP-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53005FA	SHEEP-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53005KA	SHEEP-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53005LA	SHEEP-LIVER	00 NOT SPECIFIED (NO CONSUMPTION)	0F3876	P 1.000000	1.000000		100.00	1.000000
53005MA	SHEEP-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53005MA	SHEEP-LEAN	31 COOKED-FRESH OR CANNED	0F3876	P 0.100000	0.100000		100.00	0.100000
53006BA	PORK-MEAT BYP	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006BB	PORK-OTH ORGAN	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000
53006BB	PORK-OTH ORGAN	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.200000	0.200000		100.00	0.200000
53006FA	PORK-FAT	10 RAW-FRESH OR NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	21 COOKED-NFS	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	23 COOKED-FRESH-BOILED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	25 COOKED-FRESH-FRIED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006FA	PORK-FAT	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.050000	0.050000		100.00	0.050000
53006KA	PORK-KIDNEY	21 COOKED-NFS	0F3876	P 0.200000	0.200000		100.00	0.200000

CHEMICAL	STUDY TYPE	EFFECTS	REFERENCE DOSES	DATA GAPS/COMMENTS	STATUS
Myclobutanil (Systane/Rally) Caswell #723K CAS No. 88671-89-0 A.I. CODE: 128857 CFR No. 180.443 185.4350	2yr feeding- rat NOEL= 2.4900 mg/kg 50.00 ppm LEL= 9.8400 mg/kg 200.00 ppm ONCO: E (RfD/PR Committee)	Testicular atrophy. No evidence of carcinogenicity in rats or mice.	ADI UF -->100 OPP RfD= 0.025000 EPA RfD= 0.000000	No data gaps.	HED reviewed 01/27/88 EPA verified 02/25/88 WHO reviewed 1992 RfD/PR reviewed 04/28/94 EPA deferred 04/28/94 On IRIS.

FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
53006LA	PORK-LIVER	21 COOKED-NFS	0F3876	P 1.000000	1.000000		100.00	1.000000
53006LA	PORK-LIVER	25 COOKED-FRESH-FRIED	0F3876	P 1.000000	1.000000		100.00	1.000000
53006MA	PORK-LEAN	21 COOKED-NFS	0F3876	P 0.100000	0.100000		100.00	0.100000
53006MA	PORK-LEAN	25 COOKED-FRESH-FRIED	0F3876	P 0.100000	0.100000		100.00	0.100000
53006MA	PORK-LEAN	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	0F3876	P 0.100000	0.100000		100.00	0.100000
55008BA	TURKEY-BYP	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008BA	TURKEY-BYP	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008LA	TURKEY ORGAN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008LA	TURKEY ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	31 COOKED-FRESH OR CANNED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MA	TURKEY W/O SKIN	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MB	TURKEY+SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MB	TURKEY+SKIN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55008MC	TURKEY-UNSPEC	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55013BA	POULTRY,OTH-BYP	00 NOT SPECIFIED (NO CONSUMPTION)	7F3476	P 0.020000	0.020000		100.00	0.020000
55013LA	POULTRY,ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55013MA	POULTRY,OTHER	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	22 COOKED-FRESH-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	23 COOKED-FRESH-BOILED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AA	EGGS-WHOLE	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	22 COOKED-FRESH-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	62 COOKED-FRESH OR FROZEN-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AB	EGGS-WHITE ONLY	81 COOKED-FROZEN	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	10 RAW-FRESH OR NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55014AC	EGGS-YOLK ONLY	31 COOKED-FRESH OR CANNED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015BA	CHICKEN-BYP	00 NOT SPECIFIED (NO CONSUMPTION)	7F3476	P 0.020000	0.020000		100.00	0.020000
55015LA	CHICKEN-ORGAN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55015LA	CHICKEN-ORGAN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015LA	CHICKEN-ORGAN	26 COOKED-FRESH-PICKLED,CORNED,OR CURED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	22 COOKED-FRESH-BAKED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MA	CHICKEN-W/O SKIN	31 COOKED-FRESH OR CANNED	7F3476	P 0.020000	0.020000		100.00	0.020000

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FOOD CODE	FOOD	FOOD FORM	PET.#	TOLERANCE (ppm)	ANTICIPATED RESIDUE (ppm)	AR STATISTIC TYPE	% CROP TREATED	RES. VALUE USED IN TAS RUN (ppm)
55015MA	CHICKEN-W/O SKIN	53 COOKED-CANNED-BOILED	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MB	CHICKEN+SKIN	21 COOKED-NFS	7F3476	P 0.020000	0.020000		100.00	0.020000
55015MB	CHICKEN+SKIN	25 COOKED-FRESH-FRIED	7F3476	P 0.020000	0.020000		100.00	0.020000

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Chemical: Myclobutanil

PC Code:
128857

HED File Code: 11100 Other Chemistry Documents
Memo Date: 6/18/1997
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